

### ***Remarks***

Reconsideration of this Application is respectfully requested.

Upon entry of the foregoing amendment, claims 1-3, 5-8, 10-13, 15-18, 20-26, 28-31, 33-36 and 44-59 are pending in the application, with claims 1, 8, 24, 31 and 44 being the independent claims. Claims 4, 9, 14, 27, 32, 37, 60 and 61 are sought to be cancelled without prejudice to or disclaimer of the subject matter therein. Claims 1, 8, 24, 31, 33, 44 and 47 are sought to be amended. These changes are believed to introduce no new matter, and their entry is respectfully requested.

Based on the above amendment and the following remarks, Applicants respectfully request that the Examiner reconsider all outstanding objections and rejections and that they be withdrawn.

#### ***I. Support for Claim Amendments***

Support for the amendments to claims 1, 8, 24, 31, 33 and 47 can be found in the specification, *e.g.*, at page 22, line 29, through page 23, line 31, and in claims 4 and 9 as originally presented. Support for the amendment to claim 44 can be found in the specification, *e.g.*, at page 31, lines 4-11.

#### ***II. Claim Rejections Under 35 U.S.C. § 112, First Paragraph***

Claims 1-4, 8-12, 14-18, 20-27, 31-35, 37 and 61 were rejected under 35 U.S.C. § 112, first paragraph, as allegedly containing subject matter which was not described in the

specification in such a way as to reasonably convey to one skilled in the art that Applicants had possession of the claimed invention at the time the application was filed. (*See* Paper No. 23, page 2.) This rejection is based on the phrase "with the proviso that said transition metal binding compound is not citrate." (*See* Paper No. 23, page 2.) Applicants respectfully traverse this rejection for the reasons set forth in Applicants' previous response. (*See* Supplemental Reply filed on December 5, 2002, pages 3-9.)

Nonetheless, Applicants have amended claims 1 and 24. The amended claims do not contain the phrase at issue. Therefore, the rejection under 35 U.S.C. § 112, first paragraph, is moot and should be withdrawn.

### ***III. Claim Rejections Under 35 U.S.C. § 112, Second Paragraph***

Claims 14, 37, 44 and 60 were rejected under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention. (*See* Paper No. 23, page 4.) The Examiner set forth three separate bases for this rejection, each of which is addressed in turn below.

#### ***A. Claims 14 and 37***

According to the Examiner, claims 14 and 37 are indefinite for reciting "wherein said transition element complex is 2-hydroxypyridine-N-oxide" because 2-hydroxypyridine-N-oxide is not a transition element complex. Claims 14 and 37 have been cancelled, thereby rendering this basis of rejection moot.

**B. Claim 44**

According to the Examiner, claim 44 is indefinite because "[t]he structure of the claim is unclear and the required components of the composition are thus, unclear." (Paper No. 23, page 4.) Claim 44 has been amended to more clearly indicate the subject matter that was originally intended to be encompassed by the claim. In view of the amendment to claim 44, Applicants believe that this basis of rejection has been fully accommodated and should be withdrawn.

**C. Claim 60**

According to the Examiner, claim 60 is indefinite because "it is uncertain to what the Roman numerals refer in the independent claim." (Paper No. 23, page 5.) Claim 60 has been cancelled, thereby rendering this basis of rejection moot.

**IV. Claim Rejections Under 35 U.S.C. § 102**

**A. Murad**

Claims 44-47, 54, 60 and 61 were rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by U.S. Patent No. 5,328,913 to Murad *et al.* ("Murad"). (See Paper No. 23, page 5.) Applicants respectfully traverse this rejection.

An anticipation rejection under 35 U.S.C. § 102 requires a showing that each limitation of a claim must be found in a single reference, practice, or device. *See In re Donohue*, 766 F.2d 531, 226 USPQ 619, 621 (Fed. Cir. 1985). Claim 44, as currently presented, is directed to a kit for the cultivation of a cell *in vitro*. The claimed kit comprises:

(a) at least one first container containing at least one first component selected from the group consisting of one or more cell culture media or media ingredients, and one or more cells, and  
(b) at least one second container containing at least one second component selected from the group consisting of one or more transition metal binding compounds and at least one transition element complex, said complex comprising at least one transition element or a salt or ion thereof complexed to at least one transition metal binding compound. Murad does not teach a kit having all of the elements recited in claim 44. Therefore, Murad cannot and does not anticipate claim 44 or any of the claims that depend therefrom.

Claim 54 is directed to the medium of claim 1, wherein said medium is a 1X medium formulation. Claim 1 is directed to a *serum-free* cell culture medium. The medium of Murad includes calf serum. (See Murad at column 5, lines 17-24 and 26-29.) Therefore, Murad cannot and does not anticipate claim 54.

Applicants respectfully request that the rejection under 35 U.S.C. § 102(b) based on Murad be reconsidered and withdrawn.

***B. Testa***

Claims 44-47, 54, 60 and 61 were rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by Testa, U. *et al.*, *Br. J. Haematol.* 60:491-502 (1985) ("Testa"). (See Paper No. 23, page 6.) Applicants respectfully traverse this rejection.

Claim 44, as currently presented, is directed to a kit for the cultivation of a cell *in vitro*. The claimed kit comprises: (a) at least one first container containing at least one first component selected from the group consisting of one or more cell culture media or media ingredients, and one or more cells, and (b) at least one second container containing at least

one second component selected from the group consisting of one or more transition metal binding compounds and at least one transition element complex, said complex comprising at least one transition element or a salt or ion thereof complexed to at least one transition metal binding compound. Testa does not teach a kit having all of the elements recited in claim 44. Therefore, Testa cannot and does not anticipate claim 44 or any of the claims that depend therefrom.

Claim 54 is directed to the medium of claim 1, wherein said medium is a 1X medium formulation. Claim 1 is directed to a *serum-free* cell culture medium. The medium of Testa includes fetal calf serum. (See Testa at page 492, fourth paragraph under "Materials and Methods".) Therefore, Testa cannot and does not anticipate claim 54.

Applicants respectfully request that the rejection under 35 U.S.C. § 102(b) based on Testa be reconsidered and withdrawn.

**C. Waymouth**

Claims 1-4, 8, 11, 12, 15-18, 20-27, 31, 34, 35, 44-47, 54, 55 and 61 were rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by Waymouth, C., *Methods for Preparation of Media, Supplements, and Substrata for Serum-Free Animal Cell Culture*, pp. 23-68 (1984) ("Waymouth"). (See Paper No. 23, page 6.) Applicants respectfully traverse this rejection.

This rejection is based on the inclusion of pyridoxin-HCl in complete medium MAB87/3, as set forth in Waymouth at page 48, Table I. Independent claims 1, 8 and 31, as currently presented, are directed to serum free cell culture media comprising at least one transition metal binding compound or at least one transition element complex, said complex

comprising at least one transition element or a salt or ion thereof complexed to at least one transition metal-binding compound, wherein the media are capable of supporting the cultivation of a cell *in vitro*, and wherein the transition metal binding compound is selected from the transition metal binding compounds set forth in the claims. Waymouth does not describe a serum free culture medium containing any of the transition metal binding compounds specified in claims 1, 8 or 31. Therefore, Waymouth cannot and does not anticipate claims 1, 8, 31 or any of the claims that depend therefrom.

Claim 44, as currently presented, is directed to a kit for the cultivation of a cell *in vitro*. The claimed kit comprises: (a) at least one first container containing at least one first component selected from the group consisting of one or more cell culture media or media ingredients, and one or more cells, and (b) at least one second container containing at least one second component selected from the group consisting of one or more transition metal binding compounds and at least one transition element complex, said complex comprising at least one transition element or a salt or ion thereof complexed to at least one transition metal binding compound. Waymouth does not teach a kit having all of the elements recited in claim 44. Therefore, Waymouth cannot and does not anticipate claim 44 or any of the claims that depend therefrom.

Applicants respectfully request that the rejection under 35 U.S.C. § 102(b) based on Waymouth be reconsidered and withdrawn.

**D.      *Landschulz***

Claims 1-4, 8, 9, 11, 12, 15-18, 20-27, 31, 32, 34, 35, 44-47, 54, 60 and 61 were rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by Landschulz *et al.*, *J. Cell*

*Biol.* 98:596-601 (1984) ("Landschulz"). (See Paper No. 23, page 6.) Applicants respectfully traverse this rejection.

This rejection is based on the use of ferric pyridoxal isonicotinoyl hydrazone (FePIH) by Landschulz in a chemically defined medium. Independent claims 1, 8 and 31, as currently presented, are directed to serum free cell culture media comprising at least one transition metal binding compound or at least one transition element complex, said complex comprising at least one transition element or a salt or ion thereof complexed to at least one transition metal-binding compound, wherein the media are capable of supporting the cultivation of a cell *in vitro*, and wherein the transition metal binding compound is selected from the transition metal binding compounds set forth in the claims. Landschulz does not describe a serum free culture medium containing any of the transition metal binding compounds specified in claims 1, 8 or 31. Therefore, Landschulz cannot and does not anticipate claims 1, 8, 31 or any of the claims that depend therefrom.

Claim 44, as currently presented, is directed to a kit for the cultivation of a cell *in vitro*. The claimed kit comprises: (a) at least one first container containing at least one first component selected from the group consisting of one or more cell culture media or media ingredients, and one or more cells, and (b) at least one second container containing at least one second component selected from the group consisting of one or more transition metal binding compounds and at least one transition element complex, said complex comprising at least one transition element or a salt or ion thereof complexed to at least one transition metal binding compound. Landschulz does not teach a kit having all of the elements recited in claim 44. Therefore, Landschulz cannot and does not anticipate claim 44 or any of the claims that depend therefrom.

Applicants respectfully request that the rejection under 35 U.S.C. § 102(b) based on Landschulz be reconsidered and withdrawn.

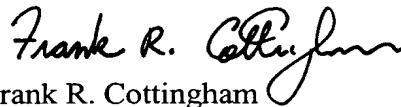
### ***Conclusion***

All of the stated grounds of objection and rejection have been properly traversed, accommodated, or rendered moot. Applicants therefore respectfully request that the Examiner reconsider all presently outstanding objections and rejections and that they be withdrawn. Applicants believe that a full and complete reply has been made to the outstanding Office Action and, as such, the present application is in condition for allowance. If the Examiner believes, for any reason, that personal communication will expedite prosecution of this application, the Examiner is invited to telephone the undersigned at the number provided.

Prompt and favorable consideration of this Amendment and Reply is respectfully requested.

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.



Frank R. Cottingham  
Attorney for Applicants  
Registration No. 50,437

Date: Aug. 5, 2003

1100 New York Avenue, N.W.  
Washington, D.C. 20005-3934  
(202) 371-2600